



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Tornier
Mrs. Severine Bonneton
Regulatory Affairs Specialist
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex
FRANCE

Re: K112144

Trade/Device Name: Aequalis Shoulder Fracture System
Aequalis Reversed Shoulder Prosthesis
Aequalis Reversed Fracture Shoulder Prosthesis

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: PHX, KWS

Dated: February 13, 2012

Received: February 15, 2012

Dear Mrs. Bonneton:

This letter corrects our substantially equivalent letter of March 13, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): *K112144*

Device Name: Aequalis Shoulder Fracture System
 Aequalis Reversed Shoulder Prosthesis
 Aequalis Reversed Fracture Shoulder Prosthesis

Indications For Use:**Aequalis Shoulder Range (except Aequalis for Fracture):**

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis.
 Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

Aequalis monobloc stem is for use with cemented applications and is labeled as such.

Aequalis Press-Fit stem is for uncemented applications and is labeled as such.

Glenoid component is for use with cemented applications and is labeled as such.

Aequalis for Fracture:

Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
 Revision surgery when other treatments or devices have failed.

Aequalis fracture stem is for cemented use.

Aequalis Reversed Shoulder Prosthesis:

The Aequalis Reversed Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to implant a base-plate and a sphere of Aequalis Reversed range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

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Aequalis Reversed Fracture Shoulder Prosthesis:

The *Aequalis Reversed Fracture Shoulder Prosthesis* is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain or significant disability following arthropathy associated to a grossly deficient rotator cuff joint:

- in case of traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures, or
- in case of bone defect in proximal humerus.

The *Aequalis Reversed Fracture Shoulder Prosthesis* is also indicated for prosthetic revisions with a grossly deficient rotator cuff joint when other treatments or devices have failed.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemiprosthesia adaptor and the union screw can be adapted to the humeral components in order to transform the *Aequalis Reversed Fracture Shoulder Prosthesis* into a non reversed hemi-prosthesis.

When, in case of revision of a *Aequalis Reversed Fracture Shoulder Prosthesis*, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of *Aequalis Reversed* range again, the use of the hemi-prosthesia adaptor and the union screw allows for the transformation of the *Aequalis Reversed Fracture Shoulder Prosthesis* into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

The *Aequalis Reversed Fracture Shoulder* humeral stem is used in association with the glenoid components of the *Aequalis Reversed Shoulder Prosthesis*.

The *Aequalis Reversed Fracture Shoulder* humeral stem is for cemented use only.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112144

Summary of Safety and Effectiveness information

Special 510(k) Premarket Notification – Aequalis Shoulder Fracture System, Aequalis Reversed Shoulder Prosthesis, Aequalis Reversed fracture Shoulder Prosthesis

Date prepared: February 13th, 2012

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: *Aequalis Shoulder Fracture System*
Common name: Hemi or Total Shoulder Prosthesis
Classification name: 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

Trade name: *Aequalis Reversed Shoulder Prosthesis*
Common name: Total-Shoulder System and Hemi-Shoulder System
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Trade name: *Aequalis Reversed Fracture Shoulder Prosthesis*
Common name: Total-Shoulder System and Hemi-Shoulder System
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier – France

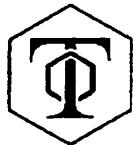
3) Applicant

Tornier, Inc.
7701 France Avenue South
Edina MN 55345 – USA

4) Company contact

Tornier
Mrs Séverine Bonneton
Regulatory affairs Specialist
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
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SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

5) Classification

For the Aequalis Shoulder Fracture System:

Device class: Class II
Classification panel: Orthopedic
Product code: KWS

For the Aequalis Reversed Shoulder Prosthesis:

Device class: Class II
Classification panel: Orthopedic
Product code: KWS

For the Aequalis Reversed Fracture Shoulder Prosthesis:

Device class: Class II
Classification panel: Orthopedic
Product code: KWS

6) Equivalent / Predicate device

For the Aequalis Fracture Shoulder System:

Aequalis Shoulder System, TORNIER SA, K952928, K041339, K043077, K060209
Aequalis Fracture Shoulder System, TORNIER SA, K994392, K003728, K032679, K043077, K060209

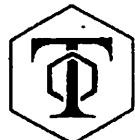
For the Aequalis Reversed Shoulder Prosthesis:

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873, K050316, K061439, K081059
Aequalis Shoulder System, TORNIER SA, K952928, K012212, K041339, K060209

For the Aequalis Reversed Fracture Shoulder Prosthesis:

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873, K050316, K061439, K081059
Aequalis Fracture Shoulder System, TORNIER SA, K994392, K003728, K032679, K043077, K060209.
Delta Xtend Reverse Shoulder System, DEPUY, K062250, K071379.
Delta Shoulder, DEPUY, K021478
Aequalis Reversed Adapter, TORNIER SA, K071948

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7) Device description

For the Aequalis Fracture Shoulder System:

The usual goal of total shoulder replacement and hemi-arthroplasty of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The *Aequalis Shoulder Fracture System* is intended to accomplish these goals. With the *Aequalis Shoulder Fracture System*, the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Thus the *Aequalis Shoulder Fracture System* is intended for use as a total shoulder replacement system, or as a hemi-shoulder. The modular nature of the system allows for the later conversion of a primary hemi-arthroplasty to a total shoulder replacement.

For the Aequalis Reversed Shoulder Prosthesis:

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.

The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

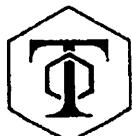
For the Aequalis Reversed Fracture Shoulder Prosthesis:

The *Aequalis Reversed Fracture Shoulder Prosthesis* is intended to be used to relieve pain or significant disability following massive cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Fracture Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm and its *Aequalis Fracture Shoulder* humeral stem-like design allows to facilitate the bone reconstruction and improve the tuberosity healing and fixation.

The *Aequalis Reversed Fracture Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

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The present submission corresponds to the following modification:

- Addition of a new coating subcontractor (hydroxyapatite coating): APS Materials, Inc. on titanium components (stem and baseplate).

All the prostheses of this file are strictly identical to the previously cleared devices except for the coating supplier. The indications for use of each device are not modified.

8) Materials (modified components)

For the Aequalis Fracture Shoulder System:

The humeral implant is manufactured from titanium alloy (Ti6Al4V) according to ISO standard 5832-3

The hydroxyapatite coating conforms to the ASTM standard F1185.

For the Aequalis Reversed Shoulder Prosthesis:

The base of the glenoid implant is manufactured from titanium alloy (Ti6Al4V) according to ISO standard 5832-3.

The hydroxyapatite coating conforms to the ASTM standard F1185.

For the Aequalis Reversed Fracture Shoulder Prosthesis:

The humeral component is manufactured from titanium alloy (Ti6Al4V) according to ISO standard 5832-3.

The hydroxyapatite coating conforms to the ASTM standard F1185.

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9) Indications

Aequalis Shoulder Range (except Aequalis for Fracture):

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

Aequalis monobloc stem is for use with cemented applications and is labeled as such.

Aequalis Press-Fit stem is for uncemented applications and is labeled as such.

Glenoid component is for use with cemented applications ad is labeled as such.

Aequalis for Fracture:

Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.

Revision surgery when other treatments or devices have failed.

Aequalis fracture stem is for cemented use.

Aequalis Reversed Shoulder Prosthesis:

The Aequalis Reversed Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of Aequalis Reversed range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components

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Aequalis Reversed Fracture Shoulder Prosthesis:

The *Aequalis Reversed Fracture Shoulder Prosthesis* is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain or significant disability following arthropathy associated to a grossly deficient rotator cuff joint:

- in case of traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures, or
- in case of bone defect in proximal humerus.

The *Aequalis Reversed Fracture Shoulder Prosthesis* is also indicated for prosthetic revisions with a grossly deficient rotator cuff joint when other treatments or devices have failed.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemiprosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the *Aequalis Reversed Fracture Shoulder Prosthesis* into a non reversed hemiprosthesis.

When, in case of revision of a *Aequalis Reversed Fracture Shoulder Prosthesis*, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of *Aequalis Reversed* range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the *Aequalis Reversed Fracture Shoulder Prosthesis* into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

The *Aequalis Reversed Fracture Shoulder* humeral stem is used in association with the glenoid components of the *Aequalis Reversed Shoulder Prosthesis*.

The *Aequalis Reversed Fracture Shoulder* humeral stem is for cemented use only.

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